

109TH CONGRESS  
1ST SESSION

# H. R. 3196

To amend the Public Health Service Act to expand the scope of information required for the data bank on clinical trials of drugs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 30, 2005

Mr. WAXMAN (for himself, Mr. MARKEY, Mr. BROWN of Ohio, Ms. SCHAKOWSKY, Mr. GENE GREEN of Texas, Mr. ALLEN, Mr. GEORGE MILLER of California, Mr. PALLONE, Mr. BERRY, Ms. SLAUGHTER, Mr. STUPAK, Mr. McDERMOTT, Mr. HINCHEY, Mr. FRANK of Massachusetts, Mr. OBERSTAR, Mr. ANDREWS, Mr. MEEKS of New York, Mr. DELAHUNT, Mr. McNULTY, Mr. BERMAN, Mr. WEXLER, Ms. WOOLSEY, Ms. HERSETH, Mr. MCGOVERN, Mr. GRIJALVA, Mr. SANDERS, Mr. WEINER, Mr. CONYERS, Mr. KUCINICH, Mr. KENNEDY of Rhode Island, Mr. OLVER, and Mr. ABERCROMBIE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to expand the scope of information required for the data bank on clinical trials of drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Fair Access to Clinical  
5 Trials Act”.

1 **SEC. 2. CLINICAL TRIALS DATA BANK.**

2 (a) IN GENERAL.—Title IV of the Public Health  
3 Service Act (42 U.S.C. 281 et seq.) is amended—

4 (1) in section 402, by striking subsection (j);  
5 and

6 (2) by inserting after section 402 the following  
7 section:

8 **“SEC. 402A. CLINICAL TRIALS DATA BANK.**

9 “(a) IN GENERAL.—

10 “(1) DATA BANK.—The Secretary, acting  
11 through the Director of NIH, shall establish, main-  
12 tain, and operate a data bank of information on clin-  
13 ical trials (including premarket and postmarket  
14 trials) for drugs, biological products, and devices.  
15 The activities of the data bank shall be integrated  
16 and coordinated with related activities of other agen-  
17 cies of the Department of Health and Human Serv-  
18 ices, and to the extent practicable, coordinated with  
19 other data banks containing similar information.

20 “(2) CONSULTATION.—The Secretary shall es-  
21 tablish the data bank after consultation with the  
22 Commissioner of Food and Drugs, the directors of  
23 the appropriate agencies of the National Institutes  
24 of Health (including the National Library of Medi-  
25 cine), and the Director of the Centers for Disease  
26 Control and Prevention.

1 “(b) COLLECTION AND DISSEMINATION OF INFORMA-  
2 TION.—

3 “(1) COLLECTION.—In carrying out subsection  
4 (a), the Secretary shall collect, catalog, store, and  
5 disseminate the information described in such sub-  
6 section.

7 “(2) INCLUSION OF SUBMITTED INFORMA-  
8 TION.—All information on clinical trials required in  
9 this section to be submitted to the Secretary shall be  
10 included in the data bank as soon as practicable  
11 after the Secretary receives the information, subject  
12 to the provisions of this section.

13 “(3) DISSEMINATION.—The Secretary shall dis-  
14 seminate information in the data bank through in-  
15 formation systems, which shall include toll-free tele-  
16 phone communications available to members of the  
17 public, to health care providers, and to researchers.

18 “(c) TRIALS SUBJECT TO REQUIREMENTS.—

19 “(1) TRIALS OF SAFETY AND EFFECTIVE-  
20 NESS.—All clinical trials, whether federally funded  
21 or privately funded, conducted to test the safety or  
22 effectiveness (including comparative effectiveness) of  
23 a drug, biological product, or device (whether clinical  
24 trials of approved products or unapproved products)

1 are subject to the requirements of this section, ex-  
2 cept as provided in paragraph (2).

3 “(2) EXCEPTIONS.—The requirements of para-  
4 graph (1) do not apply to any of the following:

5 “(A) A clinical trial to determine the safe-  
6 ty of a use of a drug if the trial is designed  
7 solely to detect major toxicities in the drug or  
8 to investigate pharmacokinetics, except that the  
9 requirements of such paragraph do apply if the  
10 trial is designed solely to investigate pharmaco-  
11 kinetics in a special population or populations.

12 “(B) A small clinical trial to determine the  
13 feasibility of a device, or a trial to test proto-  
14 type devices where the primary focus is feasi-  
15 bility.

16 “(3) CERTAIN TRIALS.—The data bank may in-  
17 clude information on a clinical trial described in sub-  
18 paragraph (A) or (B) of paragraph (2) with the con-  
19 sent of the responsible person for the trial.

20 “(4) RULE OF CONSTRUCTION.—This section  
21 may not be construed as applying to any classified  
22 information (as defined in subsection (1)).

23 “(d) REQUIRED INFORMATION.—

24 “(1) REGISTRATION OF TRIAL.—

1           “(A) IN GENERAL.—Before commencing a  
2           clinical trial that is subject to subsection (c)(1),  
3           the responsible person for the trial shall register  
4           the trial with the Secretary. Such a registration  
5           shall be in such form and be submitted in such  
6           manner as the Secretary requires, and shall in-  
7           clude the following information:

8                   “(i) The medical condition being stud-  
9                   ied.

10                  “(ii) A scientific title for the trial that  
11                  includes the name of the intervention, the  
12                  condition, and the outcome being studied.

13                  “(iii) A statement of whether the trial  
14                  has undergone research ethics review. The  
15                  statement shall provide the date on which  
16                  approval was obtained pursuant to such re-  
17                  view, or shall provide that such review is  
18                  pending. In the case of a pending review,  
19                  when approval is obtained, the responsible  
20                  person shall provide an update that pro-  
21                  vides the date of the approval.

22                  “(iv) The anticipated start date for  
23                  the trial.

1 “(v) The purpose of the trial, includ-  
2 ing a statement of the interventions and  
3 comparisons involved.

4 “(vi) The eligibility criteria for par-  
5 ticipation in the clinical trial.

6 “(vii) The funding source or sources  
7 of the trial.

8 “(viii) A statement that—

9 “(I) identifies the product as an  
10 unapproved product or as an approved  
11 product, as applicable; and

12 “(II) in the case of an approved  
13 product, identifies the trial as inves-  
14 tigating the approved use of the prod-  
15 uct or an unapproved use of the prod-  
16 uct, as applicable.

17 “(ix) The estimated completion date  
18 for the trial. For purposes of this section,  
19 the term ‘completion date’ means the date  
20 of the final collection of data from subjects  
21 in the trial for the outcomes described in  
22 clause (vi).

23 “(x) A description of the primary and  
24 secondary outcomes to be examined in the  
25 trial, the time at which the primary and

1 secondary outcomes will be assessed, and  
2 the dates and details of any revisions to  
3 such outcomes.

4 “(xi) A statement of the hypothesis  
5 being tested in the trial.

6 “(xii) The total number of subjects  
7 anticipated to participate in the trial.

8 “(xiii) Contact information for the  
9 person to whom scientific inquiries regard-  
10 ing the trial should be made.

11 “(xiv) Information on—

12 “(I) study design;

13 “(II) methods;

14 “(III) study phase; and

15 “(IV) study type.

16 “(xv) If the trial will test the effec-  
17 tiveness of the use of a product with re-  
18 spect to a serious or life-threatening dis-  
19 ease or condition, the additional informa-  
20 tion described in subparagraph (B)(i).

21 “(xvi) With respect to an individual  
22 who is not an employee of the responsible  
23 person for the trial or of the manufacturer  
24 of the product involved, information on any  
25 agreement that the responsible person or

1 manufacturer has entered into with such  
2 individual that restricts in any manner the  
3 ability of the individual to—

4 “(I) discuss the results of the  
5 trial at a scientific meeting or any  
6 other public or private forum; or

7 “(II) publish the results of the  
8 trial, or a description or discussion of  
9 the results of the trial, in a scientific  
10 or academic journal.

11 “(xvii) After the initial submission of  
12 the registration, periodic updates to reflect  
13 changes to information provided under this  
14 subparagraph. Such updates—

15 “(I) shall be provided not less  
16 frequently than once every six months  
17 until information on the results of the  
18 trial is submitted under paragraph  
19 (2)(A) or a waiver is provided under  
20 paragraph (2)(D); and

21 “(II) shall identify the dates on  
22 which the changes were made.

23 “(B) SERIOUS OR LIFE-THREATENING DIS-  
24 EASES.—



1 “(i) IN GENERAL.—For a clinical trial  
2 that will test the effectiveness of the use of  
3 a product with respect to a serious or life-  
4 threatening disease or condition, the addi-  
5 tional information referred to in subpara-  
6 graph (A)(xv) is the following:

7 “(I) A brief summary of the trial,  
8 provided in lay language.

9 “(II) A description of the loca-  
10 tion of trial sites and the start date of  
11 the trial.

12 “(III) A point of contact for indi-  
13 viduals desiring to enroll as subjects  
14 in the trial, including a single point of  
15 contact for all trial sites.

16 “(IV) The status of the trial with  
17 respect to the enrollment of subjects,  
18 stated for the trial in general and for  
19 individual trial sites.

20 “(V) Information that may be  
21 available—

22 “(aa) under a treatment in-  
23 vestigational new drug applica-  
24 tion, or a treatment investiga-  
25 tional device exemption, that has

1           been submitted to the Secretary  
2           under section 561(c) of the Fed-  
3           eral Food, Drug, and Cosmetic  
4           Act (relating to expanded access  
5           protocols); or

6                   “(bb) as a Group C cancer  
7           drug (as defined by the National  
8           Cancer Institute).

9                   “(ii)    FORMATTING    FOR    GENERAL  
10          PUBLIC.—The information provided under  
11          clause (i) shall be in a format that can be  
12          readily accessed and understood by mem-  
13          bers of the general public, including pa-  
14          tients seeking to enroll as subjects in clin-  
15          ical trials.

16                   “(C)   LABELS OF APPROVED PRODUCTS.—  
17          If a clinical trial registered under subparagraph  
18          (A) is investigating an approved product and  
19          the label for such product is included on the  
20          Internet site of the Food and Drug Administra-  
21          tion, the information in the data bank con-  
22          cerning the trial shall include an electronic link  
23          to such label for individuals accessing the data  
24          bank through the Internet.

1           “(D) UNIQUE IDENTIFIER.—The Secretary  
2           shall assign to each clinical trial registered  
3           under subparagraph (A) a unique identifier for  
4           purposes of the data bank. The Secretary shall  
5           seek to ensure that such identifiers comply with  
6           international standards for identifying clinical  
7           trials.

8           “(E) MODIFICATIONS REGARDING RE-  
9           QUIRED INFORMATION.—Notwithstanding  
10          clauses (i) through (xvi) of subparagraph (A),  
11          requirements under such clauses may be modi-  
12          fied by the Secretary, and additional require-  
13          ments for the provision of information in reg-  
14          istrations under such subparagraph may be es-  
15          tablished by the Secretary, in order to ensure  
16          the nonmisleading disclosure of important infor-  
17          mation from clinical trials.

18          “(2) SUBMISSION OF RESULTS OF TRIAL.—

19                 “(A) IN GENERAL.—The responsible per-  
20                 son for a clinical trial that is subject to sub-  
21                 section (c)(1) shall provide to the Secretary in-  
22                 formation described in subparagraph (B) on the  
23                 results of the trial, subject to subparagraph  
24                 (D). The information shall be provided in the  
25                 form of a structured abstract and in such man-

1           ner as the Secretary may require, in a form not  
2           likely to mislead or distort the results.

3           “(B) INFORMATION.—For purposes of sub-  
4           paragraph (A), the information described in  
5           this subparagraph on the results of a clinical  
6           trial is the following:

7                   “(i) The actual completion date of the  
8                   trial and the reasons for any difference  
9                   from such actual date and the estimated  
10                  completion date submitted pursuant to  
11                  paragraph (1)(A)(ix), or, if the trial is ter-  
12                  minated prior to completion, the termi-  
13                  nation date and reasons for such termi-  
14                  nation.

15                  “(ii) Primary and secondary out-  
16                  comes, presented succinctly as quantitative  
17                  data and as tests of hypotheses.

18                  “(iii) Information on the number and  
19                  type of significant adverse events in sub-  
20                  jects that may be associated with the prod-  
21                  uct involved, including such events for  
22                  which a causal relationship has not been  
23                  established.

24                  “(iv) A citation to each covered article  
25                  published in a peer-reviewed scientific or

1 academic journal. An article published in  
2 such a journal is a covered article for pur-  
3 poses of this clause if—

4 “(I) the article discusses the re-  
5 sults of the trial;

6 “(II) the responsible person or  
7 the principal investigator for the clin-  
8 ical trial contributed to the article;  
9 and

10 “(III) MEDLINE includes a ci-  
11 tation to the article.

12 “(v) A description of the process used  
13 to review the results of the trial, including  
14 a statement about whether the results have  
15 been peer reviewed by reviewers inde-  
16 pendent of the sponsor.

17 “(vi) If the trial is investigating an  
18 unapproved product or an unapproved use  
19 of an approved product, a statement, as  
20 appropriate, displayed prominently at the  
21 beginning of information in the data bank  
22 concerning the trial, that the Food and  
23 Drug Administration—

24 “(I) is currently reviewing an ap-  
25 plication for approval of such product

1 or use to determine whether the use is  
2 safe and effective;

3 “(II) has disapproved an applica-  
4 tion for approval of such product or  
5 use;

6 “(III) has reviewed an applica-  
7 tion for approval of such product or  
8 use but the application was withdrawn  
9 prior to approval or disapproval; or

10 “(IV) has not reviewed or ap-  
11 proved such product or use as safe  
12 and effective.

13 “(vii) If data from the trial has not  
14 been submitted to the Food and Drug Ad-  
15 ministration, an explanation of why it has  
16 not been submitted.

17 “(viii) A statement providing such in-  
18 formation on the protocol for the trial as  
19 may be necessary to evaluate the results of  
20 the trial. Criteria issued by the Secretary  
21 under subsection (k) shall include criteria  
22 regarding information that is required for  
23 purposes of such statements.

24 “(ix) In the group of subjects receiv-  
25 ing the product, and in each comparison

1 group of subjects, the percentage of indi-  
2 viduals who ceased participation as sub-  
3 jects and the reasons for ceasing participa-  
4 tion.

5 “(x) Basic demographic information  
6 on subjects.

7 “(xi) With respect to an individual  
8 who is not an employee of the responsible  
9 person for the trial or of the manufacturer  
10 of the product involved, information (to the  
11 extent not submitted under paragraph  
12 (1)(A)(xvi) on any agreement that the re-  
13 sponsible person or manufacturer has en-  
14 tered into with such individual that re-  
15 stricts in any manner the ability of the in-  
16 dividual to—

17 “(I) discuss the results of the  
18 trial at a scientific meeting or any  
19 other public or private forum; or

20 “(II) publish the results of the  
21 trial, or a description or discussion of  
22 the results of the trial, in a scientific  
23 or academic journal.

24 “(xii) After the initial submission of  
25 information on the results, periodic up-

1 dates to reflect changes in the information  
2 submitted pursuant to this subparagraph.  
3 Such updates—

4 “(I) shall be provided not less  
5 frequently than once every six months  
6 during the 10-year period beginning  
7 on the date on which information on  
8 the results is due under subparagraph  
9 (C)(i); and

10 “(II) shall identify the dates on  
11 which the changes were made.

12 “(C) DUE DATE FOR RESULTS.—

13 “(i) IN GENERAL.—Information re-  
14 quired under subparagraph (A) on the re-  
15 sults of a clinical trial shall be submitted  
16 to the Secretary—

17 “(I) not later than one year after  
18 the earlier of—

19 “(aa) the estimated comple-  
20 tion date of the trial, as sub-  
21 mitted under paragraph  
22 (1)(A)(ix); or

23 “(bb) the actual completion  
24 date of the trial, or the actual  
25 date of the termination of the



1 trial before completion, as appli-  
2 cable; or

3 “(II) by such later date as may  
4 apply under an extension under clause  
5 (iii).

6 “(ii) REPORTS REGARDING DUE DATE  
7 IN EXCESS OF THREE YEARS.—If the due  
8 date under clause (i) for information on  
9 the results of a clinical trial is a date that  
10 is more than three years after the date on  
11 which the trial was registered under para-  
12 graph (1)(A), the following applies:

13 “(I) Upon the expiration of such  
14 three-year period, the responsible per-  
15 son for the trial shall submit to the  
16 Secretary a report that describes the  
17 progress being made toward submis-  
18 sion of the results.

19 “(II) For each one-year period  
20 that lapses after the submission of the  
21 report under subclause (I), the re-  
22 sponsible person shall submit to the  
23 Secretary an additional report that  
24 describes such progress, except that

1 no report is required under this sub-  
2 clause after such due date.

3 “(iii) EXTENSIONS.—

4 “(I) IN GENERAL.—The Sec-  
5 retary may provide an extension of  
6 the due date under clause (i)(I) for in-  
7 formation on the results of a clinical  
8 trial if the responsible person for the  
9 trial submits to the Secretary a writ-  
10 ten request that demonstrates good  
11 cause for the extension and provides  
12 an estimate of the date on which in-  
13 formation on the results will be sub-  
14 mitted. More than one such extension  
15 may be provided by the Secretary for  
16 the clinical trial involved.

17 “(II) EXTENSIONS REGARDING  
18 JOURNAL PUBLICATION.—

19 “(aa) ARTICLE UNDER CON-  
20 sideration for publica-  
21 tion.—With respect to the sub-  
22 mission of information on the re-  
23 sults of a clinical trial, the Sec-  
24 retary shall under subclause (I)  
25 provide an extension of 18

1 months after the due date under  
2 clause (i)(I) (or if such an exten-  
3 sion previously has been pro-  
4 vided, 18 months beginning upon  
5 the expiration of the most recent  
6 extension) if—

7 “(AA) the request  
8 under such subclause dem-  
9 onstrates that an article pro-  
10 viding the information de-  
11 scribed in subparagraph (B)  
12 has been submitted to a  
13 peer-reviewed scientific or  
14 academic journal for which  
15 references are included in  
16 MEDLINE, and the request  
17 demonstrates that the article  
18 is being considered by the  
19 journal for publication; and

20 “(BB) such request is  
21 made before the expiration  
22 of the one-year period de-  
23 scribed in clause (i)(I) (or if  
24 such an extension previously  
25 has been provided, before

1 the expiration of the most  
2 recent extension).

3 “(bb) ARTICLE ACCEPTED  
4 FOR PUBLICATION.—If the re-  
5 sponsible person for a clinical  
6 trial has received an extension  
7 under item (aa) regarding the  
8 trial, the Secretary shall provide  
9 an additional extension of six  
10 months, beginning upon the expi-  
11 ration of such first extension, if  
12 the person demonstrates to the  
13 Secretary, before the expiration  
14 of the first extension, that the ar-  
15 ticle involved has been accepted  
16 for publication by a journal re-  
17 ferred to in such item.

18 “(cc) PUBLICATION DURING  
19 PERIOD OF EXTENSION.—With  
20 respect to an extension under  
21 item (aa) or (bb), if during the  
22 period of extension the article in-  
23 volved is published in a journal  
24 referred to in item (aa)—

1 “(AA) the extension  
2 terminates upon publication  
3 of the article; and

4 “(BB) the due date  
5 under clause (i) regarding  
6 the clinical trial involved be-  
7 comes the date of such pub-  
8 lication.

9 “(D) WAIVERS REGARDING RESULTS OF  
10 TRIAL.—With respect to the requirement under  
11 subparagraph (A) to submit to the Secretary in-  
12 formation on the results of a clinical trial, the  
13 Secretary may waive the requirement upon a  
14 written request to the Secretary by the respon-  
15 sible person for the trial if the Secretary deter-  
16 mines that extraordinary circumstances justify  
17 the waiver and that providing the waiver is in  
18 the public interest or consistent with the protec-  
19 tion of the public health. The Secretary shall  
20 ensure that information on each such waiver is  
21 included in the data bank.

22 “(3) UPDATES; TRACKING OF CHANGES IN SUB-  
23 MITTED INFORMATION.—The Secretary shall ensure  
24 that updates submitted to the Secretary under para-  
25 graphs (1)(A)(xvii) and (2)(B)(xii) do not result in

1 the removal from the data bank of the original sub-  
2 missions or of any preceding updates, and that in-  
3 formation in the data bank is presented in a manner  
4 that enables users to readily access each original  
5 submission and to track the changes made by the  
6 updates.

7 “(e) ENFORCEMENT.—

8 “(1) EFFECT OF FAILURE TO PROVIDE INFOR-  
9 MATION.—In the case of a clinical trial that is sub-  
10 ject to subsection (c)(1):

11 “(A) Subject to paragraph (2), if the Sec-  
12 retary determines that with respect to the trial  
13 the responsible person is not in compliance with  
14 requirements under subsection (d) to submit in-  
15 formation to the Secretary, the following ap-  
16 plies:

17 “(i) Such person is subject to a civil  
18 penalty in accordance with paragraph (3).

19 “(ii) The person is, during the period  
20 of such noncompliance, ineligible for any  
21 award from the Secretary of a grant, coop-  
22 erative agreement, or contract for the con-  
23 duct of any trial that is subject to sub-  
24 section (c)(1), including all current awards

1 for such trials, except that such period of  
2 ineligibility may not exceed five years.

3 “(iii) The person is subject to the  
4 sanction described in paragraph (4) (relat-  
5 ing to the investigational use of products)  
6 if the noncompliance is serious or repeated.

7 “(B) The submission to the Secretary of  
8 information under subsection (d) that is false or  
9 misleading constitutes noncompliance for pur-  
10 poses of subparagraph (A).

11 “(2) PROCEDURES REGARDING NONCOMPLI-  
12 ANCE.—

13 “(A) NOTICE OF NONCOMPLIANCE.—With  
14 respect to a clinical trial that is subject to sub-  
15 section (c)(1), if the Secretary determines that  
16 the responsible person involved has not sub-  
17 mitted information to the Secretary in accord-  
18 ance with subsection (d), the Secretary—

19 “(i) shall transmit to such person a  
20 notice specifying the required information  
21 and stating that the person will be subject  
22 to applicable sanctions referred to in para-  
23 graph (1)(A) if the information is not sub-  
24 mitted to the Secretary within 90 days

1 after the date on which the notice is trans-  
2 mitted;

3 “(ii) shall through the notice inform  
4 the person that under subsection (h) the  
5 person is being identified in the data bank  
6 as a noncompliant person; and

7 “(iii) shall through the notice inform  
8 the person of the provisions of paragraph  
9 (8).

10 “(B) FAILURE TO CORRECT NONCOMPLI-  
11 ANCE.—Upon the expiration of the 90-day pe-  
12 riod beginning on the date on which the Sec-  
13 retary transmits a notice under subparagraph  
14 (A) to a responsible person, the Secretary shall  
15 impose on such person the sanctions referred to  
16 in clauses (i) and (ii) of paragraph (1)(A) if the  
17 information involved has not been submitted to  
18 the Secretary, except that the Secretary may  
19 elect not to impose such a sanction or sanctions  
20 if the Secretary determines that the noncompli-  
21 ance involved is not serious or repeated.

22 “(3) AMOUNT OF CIVIL PENALTY; HEARING  
23 PROCEDURES.—With respect to a civil penalty im-  
24 posed under paragraph (1)(A)(i) on a responsible  
25 person:



1           “(A) The amount of the penalty shall be  
2           not more than a total of \$15,000 for all viola-  
3           tions adjudicated in a single proceeding in the  
4           case of an individual, and not more than  
5           \$10,000 per day until the violation is corrected  
6           in the case of any other person, except that if  
7           the person is a nonprofit entity the penalty may  
8           not exceed a total of \$15,000 for all violations  
9           adjudicated in a single proceeding.

10           “(B) The provisions of paragraphs (3)  
11           through (5) of section 303(f) of the Federal  
12           Food, Drug, and Cosmetic Act apply to the im-  
13           position of such a penalty to the same extent  
14           and in the same manner as such provisions  
15           apply to a penalty imposed under such section  
16           303(f).

17           “(4) ELIGIBILITY FOR INVESTIGATIONAL USE  
18           EXEMPTIONS.—In any case in which the noncompli-  
19           ance referred to in paragraph (1)(A) is serious or re-  
20           peated, the Secretary may, upon the expiration of  
21           the 90-day period beginning on the date on which  
22           the Secretary transmits a notice under paragraph  
23           (2)(A) to the responsible person involved, consider  
24           such person to be ineligible for any future exemp-  
25           tions under section 505(i) or 520(g) of the Federal

1 Food, Drug, and Cosmetic Act for any investigation  
2 until the violation is corrected, except that such pe-  
3 riod of ineligibility may not exceed five years. The  
4 Secretary may impose such sanction only after no-  
5 tice and an opportunity for a hearing, unless a hear-  
6 ing regarding such noncompliance is held pursuant  
7 to paragraph (3) and through such hearing the Sec-  
8 retary determines that the noncompliance was seri-  
9 ous or repeated.

10 “(5) FAILURE TO SUBMIT INFORMATION ON RE-  
11 SULTS; REQUIREMENT OF REPORTS.—In any case in  
12 which the noncompliance referred to in paragraph  
13 (1)(A) is a failure to submit to the Secretary infor-  
14 mation on the results of the trial by the due date  
15 under subsection (d)(2)(C)(i), the Secretary shall  
16 order the responsible person to submit to the Sec-  
17 retary periodic reports on the progress being made  
18 toward submission of information on the results,  
19 which reports shall be submitted not less frequently  
20 that once each year until the information is sub-  
21 mitted to the Secretary.

22 “(6) RULE OF CONSTRUCTION.—With respect  
23 to a responsible person who is subject to a sanction  
24 referred to in paragraph (1)(A), this subsection may  
25 not be construed as providing that any other person

1 associated with the clinical trial involved is subject  
2 to the sanction.

3 “(7) USE OF FUNDS.—

4 “(A) IN GENERAL.—The Secretary shall  
5 deposit the funds collected under paragraph  
6 (1)(A) into an account and use such funds, in  
7 consultation with the Director of the Agency for  
8 Healthcare Research and Quality, to fund stud-  
9 ies that compare the clinical effectiveness of two  
10 or more treatments for a disease or condition.

11 “(B) FUNDING DECISIONS.—The Secretary  
12 shall award funding under subparagraph (A)  
13 based on a priority list established not later  
14 than six months after the date of enactment of  
15 the Fair Access to Clinical Trials Act by the  
16 Director of the Agency for Healthcare Research  
17 and Quality and periodically updated as deter-  
18 mined appropriate by the Director.

19 “(8) DISCLOSURE OF CERTAIN INFORMA-  
20 TION.—In the case of a responsible person to whom  
21 a notice under paragraph (2) has been transmitted,  
22 if such person has not submitted the information in-  
23 volved to the Secretary by the expiration of the 180-  
24 day period beginning on the date on which the notice  
25 was transmitted to the person, the following applies:

1           “(A) Notwithstanding section 301(j) of the  
2           Federal Food, Drug, and Cosmetic Act, section  
3           1905 of title 18, United States Code, subsection  
4           (j)(4)(C)(ii) of this section, or any other provi-  
5           sion of law, the Secretary shall begin disclosure  
6           through the data bank of the definitions of the  
7           primary and secondary outcomes for the clinical  
8           trial involved unless the definitions have already  
9           been disclosed pursuant to subsection  
10          (j)(4)(C)(ii).

11          “(B) Notwithstanding section 301(j) of the  
12          Federal Food, Drug, and Cosmetic Act, section  
13          1905 of title 18, United States Code, or any  
14          other provision of law, if the responsible person  
15          is the manufacturer or a distributor of the  
16          product involved, the Secretary shall through  
17          the data bank disclose information on the prod-  
18          uct that—

19                 “(i) is required to be submitted under  
20                 subsection (d); and

21                 “(ii) is included in any FDA applica-  
22                 tion for the product (as defined in sub-  
23                 section (l)) that the responsible person has  
24                 submitted to the Secretary.

1       “(f) TRIALS CONDUCTED OUTSIDE UNITED  
2 STATES.—

3               “(1) IN GENERAL.—If a covered person submits  
4 to the Secretary an FDA application for a product  
5 (as defined in subsection (l)), and one or more of the  
6 investigations presented to the Secretary by such  
7 person for purposes of the document are covered for-  
8 eign investigations, the person is subject to a civil  
9 penalty—

10              “(A) in any case in which information on  
11 the investigation has not, as of the date on  
12 which the application is submitted to the Sec-  
13 retary, been submitted to the data bank to the  
14 same extent as would have been required as of  
15 such date under subsection (d) if the investiga-  
16 tion had been subject to subsection (c)(1); and

17              “(B) in any case in which, after such date,  
18 information on the investigation is not sub-  
19 mitted to the data bank to the same extent as  
20 would be required if the investigation were sub-  
21 ject to subsection (c)(1).

22              “(2) PROCEDURES.—The provisions of para-  
23 graphs (2), (3), (6), and (7) of subsection (e) apply  
24 to a civil penalty under paragraph (1) to the same

1 extent and in the same manner as such provisions  
2 apply to a civil penalty under subsection (e)(1)(A).

3 “(3) DEFINITIONS.—With respect to an FDA  
4 application for a product, for purposes of this sub-  
5 section:

6 “(A) The term ‘covered foreign investiga-  
7 tion’ means an investigation that was not con-  
8 ducted in any of the States and was not subject  
9 to subsection (c)(1).

10 “(B) The term ‘covered person’ means the  
11 person who was the principal investigator or the  
12 responsible person for any of the covered for-  
13 eign investigation or investigations involved.

14 “(g) LABELING AND ADVERTISEMENTS.—

15 “(1) IN GENERAL.—If a person disseminates la-  
16 beling, or an advertisement or other descriptive  
17 printed matter, for an approved product for human  
18 use and the labeling, advertisement, or other matter  
19 refers to an investigation that is not subject to sub-  
20 section (c)(1), and if the person was the principal in-  
21 vestigator or the responsible person for the inves-  
22 tigation, the person is subject to a civil penalty—

23 “(A) in any case in which information on  
24 the investigation has not, as of the date on  
25 which the labeling, advertisement, or other mat-

1           ter enters the market, been submitted to the  
2           data bank to the same extent as would have  
3           been required as of such date under subsection  
4           (d) if the investigation had been subject to sub-  
5           section (c)(1); and

6                   “(B) in any case in which, after such date,  
7           information on the investigation is not sub-  
8           mitted to the data bank to the same extent as  
9           would be required if the investigation were sub-  
10          ject to subsection (c)(1).

11           “(2) PROCEDURES.—The provisions of para-  
12          graphs (2), (3), (6), and (7) of subsection (e) apply  
13          to a civil penalty under paragraph (1) to the same  
14          extent and in the same manner as such provisions  
15          apply to a civil penalty under subsection (e)(1)(A).

16          “(h) PUBLIC LIST OF NONCOMPLIANT RESPONSIBLE  
17          PERSONS.—In any case in which a notice of noncompli-  
18          ance is submitted to a person under subsection (e)(2)(A),  
19          (f)(2), or (g)(2), the Secretary shall include with the infor-  
20          mation in the data bank that concerns the clinical trial  
21          involved a statement, prominently displayed, that such  
22          person has not reported information to the data bank as  
23          required by law, which statement shall remain in the data  
24          bank until the information involved is submitted to the  
25          Secretary. For purposes of the preceding sentence, the

1 Secretary shall maintain a list of noncompliant persons  
2 that is available to the public.

3 “(i) COMPLIANCE AUDITS.—

4 “(1) IN GENERAL.—The Secretary shall con-  
5 duct periodic audits of responsible persons for clin-  
6 ical trials that are subject to subsection (c)(1) in  
7 order to determine whether such persons have sub-  
8 mitted information as required in subsection (d), in-  
9 cluding determining whether any of the information  
10 is false or misleading.

11 “(2) PRIORITY.—In conducting audits under  
12 subparagraph (A), the Secretary shall give priority  
13 to responsible persons for clinical trials who have at  
14 any time been included on the list under subsection  
15 (h), taking into account the number and severity of  
16 the violations involved.

17 “(j) GENERAL PROVISIONS.—

18 “(1) AUTHORITY OF SECRETARY.—

19 “(A) INCLUSION OF STATEMENTS TO  
20 AVOID MISINTERPRETATIONS.—The Secretary  
21 may include in the data bank such statements  
22 as the Secretary determines to be appropriate  
23 to assist the public in avoiding misinterpreta-  
24 tions of information in the data bank. State-  
25 ments under the preceding sentence may in-



1           clude statements regarding the data bank in  
2           general and statements regarding particular  
3           items of information submitted to the data  
4           bank. The Secretary may not under the pre-  
5           ceding sentence alter any information as sub-  
6           mitted.

7           “(B) FALSE OR MISLEADING INFORMA-  
8           TION.—If the Secretary determines that infor-  
9           mation presented or cited in the data bank is  
10          false or misleading, the Secretary shall, prompt-  
11          ly after making such determination, identify in  
12          the data bank the information as false or mis-  
13          leading (as applicable), and shall, to the extent  
14          practicable, include in the data bank an accu-  
15          rate version of the information. The Secretary  
16          shall in addition make appropriate public notifi-  
17          cation.

18          “(2) LIMITATION ON DISCLOSURES.—This sec-  
19          tion may not be construed as authorizing the disclo-  
20          sure of information through the data bank if—

21                 “(A) such disclosure would constitute a  
22                 clearly unwarranted invasion of personal pri-  
23                 vacy; or

24                 “(B) such information concerns a method  
25                 or process which as a trade secret is entitled to

1 protection within the meaning of section 301(j)  
2 of the Federal Food, Drug, and Cosmetic Act.

3 “(3) INSTITUTIONAL REVIEW BOARDS.—The  
4 Secretary shall amend part 46 of title 45, Code of  
5 Federal Regulations, and parts 50, 56, and 812 of  
6 title 21 of Code, to provide as follows:

7 “(A) That the functions of institutional re-  
8 view boards under such parts include—

9 “(i) determining whether clinical trials  
10 that are subject to subsection (c)(1) are  
11 registered under subsection (d)(1)(A); and

12 “(ii) denying the approval of the  
13 boards for such trials that are not so reg-  
14 istered.

15 “(B) That any approval of an institutional  
16 review board regarding such a trial is not effec-  
17 tive under such parts if the trial is not so reg-  
18 istered.

19 “(C) That upon request of an institutional  
20 review board for such a trial, the Secretary will  
21 provide to the board a copy of the registration  
22 for the trial under subsection (d)(1)(A) (which  
23 copy will be the registration as submitted to the  
24 Secretary, together with all updates to the reg-  
25 istration).

1 “(4) DISCLOSURE OF INFORMATION.—

2 “(A) IN GENERAL.—The Secretary shall  
3 disseminate information in the data bank  
4 through an Internet site or sites under subpara-  
5 graph (B) and through any other means deter-  
6 mined appropriate by the Secretary. Informa-  
7 tion required in this section to be submitted to  
8 the Secretary shall not be considered confiden-  
9 tial commercial information or trade secrets,  
10 notwithstanding any other provision of law.

11 “(B) INTERNET SITES.—

12 “(i) IN GENERAL.—The Secretary  
13 shall operate one or more searchable Inter-  
14 net sites for purposes of presenting to cli-  
15 nicians and researchers, and to patients  
16 seeking to enroll as subjects in clinical  
17 trials, information in the data bank. The  
18 Secretary shall ensure that—

19 “(I) such a site, or a portion of  
20 a site, is designed specifically for use  
21 by clinicians and researchers; and

22 “(II) such a site, or a portion of  
23 a site, is designed specifically for use  
24 by patients seeking to enroll as sub-  
25 jects in clinical trials.

1                   “(ii) RELATION TO CERTAIN INTER-  
2                   NET SITE.—The Secretary shall ensure  
3                   that the Internet site or portion thereof op-  
4                   erated under clause (i)(II) includes infor-  
5                   mation of the type that was available on  
6                   ClinicalTrials.gov as of the day before the  
7                   date of the enactment of the Fair Access  
8                   to Clinical Trials Act (relating to serious  
9                   or life-threatening diseases). This section  
10                  may not be construed as requiring the Sec-  
11                  retary to terminate or alter  
12                  ClinicalTrials.gov, or as prohibiting the  
13                  Secretary from terminating or altering  
14                  such site.

15               “(C) REGISTRATION INFORMATION; DATE  
16               OF DISCLOSURE.—In the case of information  
17               regarding a clinical trial that is submitted to  
18               the Secretary under subsection (d)(1), disclo-  
19               sures of the information through the data bank  
20               shall, subject to subsection (e)(8), begin in ac-  
21               cordance with the following:

22                   “(i) All such disclosures shall begin  
23                   promptly after the registration involved is  
24                   submitted to the Secretary, other than dis-

1 closure of the definitions of the primary  
2 and secondary outcomes.

3 “(ii) Disclosure of the definition of  
4 the primary and secondary outcomes shall  
5 begin at the same time as disclosure of the  
6 results of the trial begin under subpara-  
7 graph (D)(i), unless the responsible person  
8 for the trial requests earlier disclosure, or  
9 unless the Secretary requires earlier disclo-  
10 sure pursuant to subparagraph (E)(ii).

11 “(D) RESULTS OF TRIAL; DATE OF DIS-  
12 CLOSURE.—

13 “(i) IN GENERAL.—In the case of in-  
14 formation regarding a clinical trial that is  
15 submitted to the Secretary under sub-  
16 section (d)(2)(A), disclosures of the infor-  
17 mation through the data bank shall begin  
18 promptly after the information is sub-  
19 mitted to the Secretary, subject to clause  
20 (ii).

21 “(ii) WAIVER REGARDING RESULTS  
22 OF TRIAL.—In the case of information on  
23 waivers that is contained in the data bank  
24 under subsection (d)(2)(D), disclosures of  
25 the information through the data bank

1           shall begin promptly after the waiver is  
2           provided.

3           “(E) STUDY REGARDING DATE FOR DIS-  
4           CLOSURE OF PRIMARY AND SECONDARY OUT-  
5           COMES; AUTHORITY OF SECRETARY.—

6                   “(i) IN GENERAL.—The Secretary, in  
7                   consultation with appropriate government  
8                   agencies, shall conduct a study to deter-  
9                   mine whether the delay in disclosure of the  
10                  definitions of the primary and secondary  
11                  outcomes under clause (ii) of subparagraph  
12                  (C), relative to the timing of disclosures  
13                  under clause (i) of such subparagraph, is  
14                  consistent with the protection of the public  
15                  health. Not later than three years after the  
16                  date of the enactment of the Fair Access  
17                  to Clinical Trials Act, the Secretary shall  
18                  complete the study and submit to the ap-  
19                  propriate committees of the Congress a re-  
20                  port describing the findings of the study.

21                   “(ii) AUTHORITY OF SECRETARY.—If  
22                   on the basis of the study under clause (i)  
23                   the Secretary determines that the delay re-  
24                   ferred to in such clause is not consistent  
25                   with the protection of the public health,

1           the Secretary shall by regulation establish  
2           an earlier date for disclosures of the defini-  
3           tions referred to in such clause, which date  
4           may not be earlier than the date of disclo-  
5           sures under subparagraph (C)(i). A final  
6           rule shall be issued under the preceding  
7           sentence not later than one year after the  
8           date on which the report under clause (i)  
9           of this subparagraph is submitted to the  
10          appropriate committees of the Congress.

11          “(5) LIMITATION ON USE OF INFORMATION.—  
12          Information on a clinical trial that is disclosed  
13          through the data bank, including information dis-  
14          closed under subsection (e)(8), may not be used by  
15          a person other than the responsible person for the  
16          trial (or an entity acting with the permission of such  
17          person) as part of any FDA application (as defined  
18          in subsection (l)) unless the information is available  
19          in accordance with law from a source other than the  
20          data bank.

21          “(6) SUBMISSION FORMAT AND TECHNICAL  
22          STANDARDS.—

23                 “(A) IN GENERAL.—The Secretary shall,  
24                 to the extent practicable, accept submissions re-  
25                 quired in subsection (d) in an electronic format

1           and shall establish interoperable technical  
2           standards for such submissions.

3           “(B) CONSISTENCY OF STANDARDS.—To  
4           the extent practicable, the standards established  
5           under subparagraph (A) shall be consistent  
6           with standards adopted by the Consolidated  
7           Health Informatics Initiative (or a successor or-  
8           ganization to such Initiative) to the extent such  
9           Initiative (or successor) is in operation.

10          “(7) TRIALS NOT INVOLVING DRUGS, BIOLOGI-  
11          CAL PRODUCTS, OR DEVICES.—The Secretary shall  
12          establish procedures and mechanisms to allow for  
13          the voluntary submission to the Secretary of infor-  
14          mation described in subsection (d)(2)(B) on clinical  
15          trials that are not subject to subsection (c)(1). Infor-  
16          mation received by the Secretary under this para-  
17          graph shall be included in the data bank. In any  
18          case in which it is in the interest of public health,  
19          the Secretary may require that information on such  
20          trials be submitted to the Secretary. Failure to com-  
21          ply with such a requirement shall be deemed to be  
22          a failure to submit information as required under  
23          this section, and the appropriate remedies and sanc-  
24          tions under this section shall apply.



1           “(8) AWARD FOR CONDUCT OF CLINICAL TRIAL;  
2           COMPLIANCE COSTS AS DIRECT COSTS.—In admin-  
3           istering an award of a grant, contract, or coopera-  
4           tive agreement that is subject to subsection (c)(1),  
5           the Secretary shall consider the costs of complying  
6           with requirements under this section as part of the  
7           direct costs of conducting the clinical trial involved.  
8           “(k) CRITERIA.—The Secretary shall establish cri-  
9           teria regarding compliance with this section.

10          “(l) DEFINITIONS.—For purposes of this section:

11           “(1) The term ‘approved product’ means a  
12           product that is approved, licensed, or cleared for  
13           commercial distribution under section 505, 510(k),  
14           or 515 of the Federal Food, Drug, and Cosmetic Act  
15           or under section 351 of this Act.

16           “(2) The term ‘approved use’, with respect to  
17           an approved product, means a use that is an ap-  
18           proved, licensed, or cleared use of the product under  
19           a provision of law referred to in paragraph (1).

20           “(3) The term ‘biological product’ has the  
21           meaning given such term in section 351.

22           “(4) The term ‘classified’, with respect to infor-  
23           mation, means information on matters referred to in  
24           section 552(b)(1)(A) of title 5, United States Code.

1           “(5) The term ‘clinical trial’, with respect to a  
2           product, means a clinical investigation within the  
3           meaning of section 505(i) of the Federal Food,  
4           Drug, and Cosmetic Act (in the case of drug), or  
5           within the meaning of section 520(g) of such Act (in  
6           the case of a device), as applicable, except that such  
7           term does not include such an investigation that  
8           does not prospectively assign human subjects to  
9           intervention or comparison groups to study the caus-  
10          al relationship between a medical intervention and  
11          an outcome.

12           “(6) The term ‘data bank’ means the data bank  
13          under subsection (a).

14           “(7) The term ‘device’ has the meaning given  
15          such term in section 201(h) of the Federal Food,  
16          Drug, and Cosmetic Act.

17           “(8) The term ‘drug’ has the meaning given  
18          such term in section 201(g)(1) of the Federal Food,  
19          Drug, and Cosmetic Act. Such term includes a bio-  
20          logical product.

21           “(9) The term ‘FDA application’, with respect  
22          to a product, means each of the following:

23                   “(A) An application or report submitted to  
24                   the Secretary for the purpose of seeking a deci-  
25                   sion by the Secretary for the product to become

1 an approved product (as defined in paragraph  
2 (1)). Such term includes a supplement to such  
3 an application or report.

4 “(B) An application for an exemption  
5 under section 505(i) or 520(g) of the Federal  
6 Food, Drug, and Cosmetic Act (relating to in-  
7 vestigational use).

8 “(10) The term ‘MEDLINE’ means the biblio-  
9 graphic electronic data base of references to journal-  
10 published articles that is operated by the National  
11 Library of Medicine and is designated by such Li-  
12 brary as the Medical Literature, Analysis, and Re-  
13 trieval System Online.

14 “(11) The term ‘postmarket’, with respect to a  
15 clinical trial to investigate a product, means a clin-  
16 ical trial that is conducted after the product has be-  
17 come an approved product.

18 “(12) The term ‘product’ means a drug, biologi-  
19 cal product, or device.

20 “(13) The term ‘responsible person’, with re-  
21 spect to a clinical trial that is subject to subsection  
22 (c)(1), has the following meaning, as applicable:

23 “(A) In any case in which an application  
24 has with respect to the trial been submitted for  
25 an exemption under section 505(i) or

1           520(g)(2)(A) of the Federal Food, Drug, and  
2           Cosmetic Act, such term means the entity who,  
3           within the meaning of such section, is the spon-  
4           sor of the trial.

5           “(B) In any case in which such an applica-  
6           tion has not been submitted, such term means  
7           the entity who is or will be providing the largest  
8           share of the monetary support for the trial  
9           (without regard to any in-kind support for the  
10          trial), subject to the following:

11           “(i) If the Federal Government or a  
12          State is or will be providing the largest  
13          share, such term means the principal in-  
14          vestigator for the trial.

15           “(ii) If a nonprofit private entity is or  
16          will be providing the largest share, such  
17          term means the principal investigator for  
18          the trial in any case in which such entity  
19          and investigator have jointly certified to  
20          the Secretary that the investigator will be  
21          the responsible person for purposes of this  
22          section.

23           “(iii) If two or more entities provide  
24          equal monetary support for the trial and  
25          no other entity provides a greater amount

1 of monetary support, such term means  
2 each of the entities providing such equal  
3 support, other than the Federal Govern-  
4 ment or a State.

5 “(iv) Notwithstanding clauses (i)  
6 through (iii), if an entity submits to the  
7 Secretary a written request to be the re-  
8 sponsible person for purposes of this sec-  
9 tion, such term means that entity in any  
10 case in which the Secretary determines  
11 that the entity is responsible for con-  
12 ducting the trial, has access to and control  
13 over the data, has the right to publish the  
14 results of the trial, and has the responsi-  
15 bility to meet all of the requirements under  
16 this section that are applicable to respon-  
17 sible persons.

18 “(14) The term ‘unapproved product’ means a  
19 product that is not an approved product.

20 “(15) The term ‘unapproved use’, with respect  
21 to an approved product, means a use that is not an  
22 approved use.

23 “(m) AUTHORIZATION OF APPROPRIATIONS.—For  
24 the purpose of carrying out this section, there are author-  
25 ized to be appropriated such sums as may be necessary

1 for fiscal year 2005 and each subsequent fiscal year. Fees  
2 collected under section 736 or 738 of the Federal Food,  
3 Drug, and Cosmetic Act shall not be used in carrying out  
4 this section.”.

5 (b) APPLICABILITY.—With respect to section 402A of  
6 the Public Health Service Act (as added by subsection (a)  
7 of this section):

8 (1) Subject to paragraphs (2) and (3), such  
9 section 402A applies to all clinical trials that are  
10 commenced on or after the date of the enactment of  
11 this Act, or are in progress as of such date, to the  
12 extent the trials are described in subsection (c)(1) of  
13 such section and not within an exception under sub-  
14 section (c)(2) of such section.

15 (2) For purposes of paragraph (1), such section  
16 402A applies to a trial that is in progress only if the  
17 final data collection from subjects in the trial on the  
18 primary outcome has not been completed as of the  
19 date of the enactment of this Act. Such a trial be-  
20 comes subject to such section upon the expiration of  
21 30 days after such date of enactment, except that  
22 registration information required pursuant to sub-  
23 section (d)(1) of such section is due upon the expira-  
24 tion of such 30 days.

1           (3) The Secretary of Health and Human Serv-  
2       ices (referred to in this paragraph as the “Sec-  
3       retary”) shall establish procedures and mechanisms  
4       to allow for the voluntary submission to the Sec-  
5       retary of information described in subsection  
6       (d)(2)(B) of such section 402A on clinical trials that  
7       were completed prior to such date of enactment, or  
8       were in progress as of such date but not subject to  
9       paragraph (2). Information received by the Sec-  
10      retary under this paragraph shall be included in the  
11      data bank. In any case in which it is in the interest  
12      of public health, the Secretary may require that in-  
13      formation on such trials be submitted to the Sec-  
14      retary. Failure to comply with such a requirement  
15      shall be deemed to be a failure to submit informa-  
16      tion as required under such section, and the appro-  
17      priate remedies and sanctions under such section  
18      shall apply.

19           (4) Definitions applicable to such section 402A  
20      apply for purposes of this subsection.

21      (c) RULE OF CONSTRUCTION REGARDING PRIOR  
22      PROVISION.—With respect to the data bank program  
23      under section 402(j) of the Public Health Service Act as  
24      in effect on the day before the date of the enactment of  
25      this Act:

1           (1) Subsection (a) shall be construed as a  
2           transfer and modification of the program, and not as  
3           the termination of the program and the establish-  
4           ment of a different program.

5           (2) All information contained in the data bank  
6           on such day shall continue to be contained in the  
7           data bank, subject to section 402A of the Public  
8           Health Service Act (as added by subsection (a) of  
9           this section) or other applicable provisions of law.

10          (d) CONFORMING AMENDMENTS.—Chapter V of the  
11          Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351  
12          et seq.) is amended—

13               (1) in section 505(i), by adding at the end the  
14               following paragraph:

15               “(5) The provision of an exemption under paragraph  
16               (1) is subject to section 402A(e)(4) of the Public Health  
17               Service Act (relating to a data bank on clinical trials).”;  
18               and

19               (2) in section 520(g), by adding at the end the  
20               following paragraph:

21               “(8) The provision of an exemption under paragraph  
22               (2)(A) is subject to section 402A(e)(4) of the Public  
23               Health Service Act (relating to a data bank on clinical  
24               trials).”.



1 **SEC. 3. REPORTS.**

2 (a) IMPLEMENTATION REPORT.—Not later than one  
3 year after the date of enactment of this Act, the Secretary  
4 of Health and Human Services (referred to in this section  
5 as the “Secretary”) shall submit to the appropriate com-  
6 mittees of the Congress a report on the status of the im-  
7 plementation of the requirements of the amendments  
8 made by section 2 that includes a description of the num-  
9 ber and types of clinical trials for which information has  
10 been submitted under such amendments.

11 (b) DATA COLLECTION.—

12 (1) IN GENERAL.—The Secretary shall request  
13 the Institute of Medicine to enter into a contract  
14 with the Secretary for the conduct of a study con-  
15 cerning the extent to which information submitted to  
16 the data bank under section 402A of the Public  
17 Health Service Act (as added by section 2(a)) has  
18 impacted the public health.

19 (2) REPORT.—The Secretary shall ensure that  
20 the contract under paragraph (1) provides that, not  
21 later than six months after the date on which a con-  
22 tract is entered into, the Institute of Medicine will  
23 submit to the Secretary a report on the results of  
24 the study under such paragraph, and that the report  
25 may include any recommendations of the Institute  
26 for changes to the program carried out under the

1       section referred to in such paragraph that the Insti-  
2       tute considers appropriate to benefit the public  
3       health.

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